REMARKS

Status of the Present Application

The present application relates to the use of CG-containing immunostimulatory nucleic acid to modulate immune responses to antigens. Claim 205 is currently pending, and the claim defines the same invention as the claims of U.S. Patent No. 6,207,646 ("the Krieg '646 patent").

Claim 205 of the present application relates to a method for suppressing an allergic response to an antigen in a mammal by administering both an immunostimulatory nucleic acid and the antigen to the mammal. The subject matter of claim 205 is substantially the same as that of claim 3 of the Krieg '646 patent, which relates to a method for desensitizing a subject against an allergic reaction by administering to the subject a CG-containing immunostimulatory nucleic acid and the allergen.

In view of the presence of interfering subject matter, Applicants submitted a request for interference under 37 C.F.R. §1.607 on October 31, 2001, and a revised one on May 9, 2002, both of which contain a detailed explanation of the interfering claims. As set forth below, Applicants submit that claim 205 is allowable. Accordingly, Applicants respectfully request that an interference be declared.

Applicants further request expedited examination of the present application. Examination of an application in which applicants seek an interference with a patent shall be conducted with special dispatch under 37 C.F.R. §1.607 and MPEP §2307. Therefore, expedited examination, in which the present application is advanced out of turn for examination, is respectfully requested under MPEP §708.01(F).

Interview

Applicants wish to thank Examiners Q. Nguyen and D. Guzo, and Interference Practice Specialist A. Nelson, for extending the courtesy of an interview to Applicants' representatives and providing helpful suggestions on June 26, 2003. The amendments and remarks herein reflect discussion and suggestions made by the Examiners for the purpose of declaration of an interference. Since all the points raised in the Office Action and the Examiners' concerns have been addressed, Applicants respectfully request that an interference be declared.

Claim Amendments

Claims 202, 203, 204 and 206 have been canceled without prejudice or disclaimer.

Claim 205 has been amended to recite "co-administering" an immunostimulatory nucleic acid and an antigen, for which support can be found, for example, in Example VII (pages 50-52 of the specification).

No new matter has been introduced by these amendments. The Examiner is hereby requested to enter the amendments.

Applicants submit that all claim amendments presented herein or previously are made solely in the interest of expediting declaration of an interference and should not be interpreted as acquiescence to any rejections or ground of unpatentability. Applicants reserve the right to file at least one continuing application to pursue any subject matter that is canceled or removed from prosecution due to the amendments.

Priority (Pages 3-5 of the Office Action)

The Office Action reiterates the issue of priority that was stated in the previous Office Actions dated March 15, 2002 and July 29, 2002, respectively. Applicants explained in detail, in

the Amendment and Reply filed on May 9, 2002, the reasons under which claims 202-203 should be afforded the priority date of August 26, 1993. However, since claims 202 and 203 have been canceled, this issue is now moot.

Rejections under 35 U.S.C. §112, second paragraph (Pages 5-7 of the Office Action)

Claim 204 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Since claim 204 has been canceled, this rejection is now moot. Therefore, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. §102 and 35 U.S.C. §103 (Pages 7-13 of the Office Action)

Claim 202 stands rejected under 35 U.S.C. §102(e) in view of Davis (U.S. Pat. No. 5,780,448, "Davis") as evidenced by Krieg et al. (U.S. Pat. No. 6,194,388, "Krieg"); under 35 U.S.C. §103(a) as allegedly being unpatentable over Krieg in view of Davis; and under 35 U.S.C. §103(a) as allegedly being unpatentable over Krieg in view of Applicants' admission (Amendment C filed October 31, 2001 in paper No. 28, page 8, second last paragraph and page 9, second paragraph). Since claim 202 has been canceled, these rejections are now moot.

Accordingly, withdrawal of these rejections is respectfully requested.

Rejections under 35 U.S.C. §112, first paragraph (Pages 14-25 of the Office Action)

Claim 205

Claim 205 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly not being enabled. However, the Office Action states that the specification is enabling for:

A method for suppressing an allergic response to an antigen in a mammal susceptible to an allergic reaction to said antigen which stimulates production of allergy-associated IgE antibodies in the mammal, comprising parenterally co-administering to the mammal (a) an effective amount of an immunostimulatory nucleic acid in a plasmid, said immunostimulatory nucleic acid comprising 5'CG3', wherein C is unmethylated, and (b) an effective amount of the antigen provided as the antigen *per se* or as a polynucleotide encoding the antigen. (page 14, lines 11-17 of the Office Action; original emphasis)

Claim 205 has been amended to recite "co-administering". Thus, claim 205 is directed to the method recited above, which is deemed enabled by the Office Action. Accordingly, withdrawal of this rejection is respectfully requested.

Claim 204

Claim 204 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly not being enabled. This rejection is now moot in view of cancellation of claim 204. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 203 and 206

Claims 203 and 206 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not being enabled. Since claims 203 and 206 have been canceled, this rejection is now moot. Therefore, withdrawal of this rejection is respectfully requested.

Request for Declaration of Interference

Pursuant to 37 C.F.R. §1.606 and MPEP §2307.02, an interference should be declared if the application contains at least one allowable claim. Since the currently pending claim, claim 205, is allowable, declaration of an interference is appropriate. All the requirements for requesting an interference with a patent have been satisfied in Applicants' requests for interference under 37 C.F.R. §1.607 submitted on October 31, 2001 and May 9, 2002. However, for the convenience of the Examiner, a brief summary of these requirements is included below.

1. Identification of the patent:

   U.S. Patent No. 6,207,646 ("the Krieg '646 patent").

2. Presentation of a proposed count:

   The proposed count, set forth in Appendix A, would be claim 205 of the present application or claim 3 of the Krieg '646 patent[1].

3. Identification of at least one claim in the patent corresponding to the proposed count:

[1] Although claim 205 has been amended to recite "co-administering", it defines the same invention as claim 3 of the Krieg '646 patent since the Krieg '646 patent provides guidance only for co-administration of immunostimulatory nucleic acids and allergens. The Krieg '646 patent provides only a single example of *in vivo* administration of immunostimulatory nucleic acids and antigen, which is found in Example 12 (columns 42-43). Example 12 discusses the effect of immunostimulatory nucleic acids administered together with *Schistosoma mansoni* eggs on inflammatory cellular infiltrate and eosinophilia in a murine model of asthma. Thus, mice were sensitized to Schistosoma egg antigen (SEA) by injection with *S. mansoni* eggs, or were injected with *S. mansoni* eggs together with immunostimulatory nucleic acids. These mice were subsequently exposed to soluble SEA. There is no supporting evidence elsewhere in the Krieg '646 patent for *in vivo* administration of immunostimulatory nucleic acids and allergen in any manner other than co-administration. Therefore, claim 205 of the present application, as amended, defines the same invention as claim 3 of the Krieg '646 patent, and an interference is properly requested.

For the reasons set forth in Appendix B, claims 3, 11, 12, 17, 21, 25, 27, 37 and 38 of the Krieg '646 patent correspond to the proposed count.

4. Identification of at least one claim in the application corresponding to the proposed count:

Claim 205, being an alternative of the proposed count, corresponds exactly to the proposed count.

5. Application of the terms of the application claim:

Appendix C sets forth the support for claim 205.

6. The requirement under 35 U.S.C. 135(b):

Claim 204 was added to the present application on October 31, 2001, which was within a year of the issue date of the Krieg '646 patent, March 27, 2001.

Accordingly, all the requirements have been satisfied. Furthermore, claim 205 of the present application is entitled to the benefit of the priority date of January 30, 1996, while the Krieg '646 patent claims only date back to October 30, 1996[2]. Therefore, Applicants respectfully request that an interference be declared naming Applicants as the senior party.

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[2] Although the application leading to the Krieg '646 patent is listed as a continuation of U.S. Application No. 08/386,063, filed February 7, 1995 ("the '063 application"), the disclosure of the Krieg '646 patent is significantly different from that of the '063 application. In particular, there is no disclosure of the use of CpG sequences in allergic reactions in the '063 application (see attached Appendix B for a more comprehensive discussion on this point). Therefore, the Krieg '646 patent claims at issue are only entitled to the filing date of October 30, 1996.

CONCLUSION

In view of the above amendments and remarks, Applicants submit that the pending claim of this application is patentable. Accordingly, Applicants respectfully request that an interference be declared employing the proposed count set forth in Appendix A, and that Applicants be named senior party.

If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, he is encouraged to contact the undersigned at the telephone number below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 02-4800**, referencing docket no. 028723-306. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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